

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

VERAX BIOMEDICAL, INC.,

Plaintiff,

v.

AMERICAN NATIONAL RED CROSS,

Defendant.

Civil Action No.: 1:23-cv-10335-PBS

**DEFENDANT AMERICAN NATIONAL RED CROSS' ANSWER AND
AFFIRMATIVE DEFENSES TO PLAINTIFF'S COMPLAINT**

Defendant, American National Red Cross ("Red Cross"), hereby answers Plaintiff, Verax Biomedical, Inc.'s ("Verax"), Complaint as follows.

On January 19, 2024, the Court dismissed Counts One, Two, Three and Five in Verax's Complaint. *See* Memorandum and Order, ECF No. 42 (Jan. 19, 2024) ("January 19 Order"). Therefore, the Red Cross is only obligated to answer the Complaint as to Counts Four and Six. To the extent not expressly admitted, all allegations of the Complaint are denied. By admitting that the Complaint purports to quote from or characterize a particular document, the Red Cross does not admit the truth of any assertion in the referenced document. To the extent the headings in Verax's Complaint are intended to constitute factual allegations that require a response, the Red Cross denies each and every such allegation.

I. NATURE OF THE ACTION

1. Denied. On January 19, 2024, the Court found that the Red Cross is not a "person" subject to the Sherman Act. *See* January 19 Order.

2. The Red Cross admits that it manufactures and distributes lifesaving blood products, including platelets, in the United States. To the extent Paragraph 2 contains characterizations, legal argument and conclusions, no response is necessary. If a response is deemed necessary, the Red Cross denies the remaining allegations in Paragraph 2.

3. Admitted.

4. The Red Cross admits that platelets are susceptible to bacterial contamination, which can cause serious, and sometimes fatal, side effects in transfusion recipients. The Red Cross admits that U.S. Food and Drug Administration (“FDA”) regulations mandate that blood centers mitigate the risk of bacterial contamination before distributing platelets to hospital customers. The FDA has only approved three manufacturing methods for bacterial mitigation: pathogen reduction technology (“PRT”), large volume delayed sampling (“LVDS”), and a primary culture performed by the blood collection establishment followed by a secondary culture or rapid test typically performed by the hospital. Except as otherwise admitted, the Red Cross denies the allegations in Paragraph 4.

5. To the extent Paragraph 5 contains characterizations, legal argument and conclusions, no response is necessary. If a response is deemed necessary, the Red Cross denies those allegations in Paragraph 5. The Red Cross lacks knowledge or information sufficient to form a belief as to the truth of the other allegations in Paragraph 5, and on that basis denies them.

6. Denied.

7. The Red Cross admits that in July 2020, it announced that it would transition to 100% pathogen reduced platelets by 2023 and shared a multi-year, phased implementation plan with customers. Except as otherwise admitted, the Red Cross denies the allegations in Paragraph 7.

8. Denied.

9. Denied.

10. Denied.

11. Denied.

12. Denied.

13. Denied. On January 19, 2024, this Court found that the Red Cross is not a “person” subject to the Sherman Act. *See* January 19 Order.

14. Denied.

15. Denied.

16. Admitted.

17. Denied.

18. Denied.

19. Denied.

20. Denied.

21. Denied.

22. Paragraph 22 contains characterizations, legal argument and conclusions, to which no response is necessary. To the extent a response is necessary, the Red Cross denies the allegations in Paragraph 22.

II. JURISDICTION AND VENUE

23. Paragraph 23 contains characterizations, legal argument and conclusions, to which no response is necessary. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 23. However, the Red Cross refers to the jurisdictional provisions in its statutory charter. *See Am. Nat’l Red Cross v. S.G.*, 505 U.S. 247 (1992).

24. Paragraph 24 contains characterizations, legal argument and conclusions, to which no response is necessary. If a response is deemed necessary, the Red Cross does not dispute that it is subject to personal jurisdiction in Massachusetts for purposes of this action only. The Red Cross denies the remaining allegations in Paragraph 24.

25. Paragraph 25 contains characterizations, legal argument and conclusions, to which no response is necessary. If a response is deemed necessary, the Red Cross does not challenge venue for purposes of this action only. The Red Cross denies the remaining allegations in Paragraph 25.

III. PARTIES

26. The Red Cross lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 26, and on that basis denies them.

27. The Red Cross lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 27, and on that basis denies them.

28. The Red Cross admits that it exists and is organized pursuant to a statutory charter granted by Congress in the United States Code. 36 U.S.C. §§ 300101-300113. The Red Cross further admits that it does not operate for profit and that its national headquarters is in Washington, DC. The Red Cross denies any remaining allegations in Paragraph 28.

29. The Red Cross admits blood platelets are one of the products that it collects, manufactures and sells to hospitals in the United States, including in Massachusetts. The Red Cross further admits that federal law mandates that all blood centers, including the Red Cross, take FDA-approved measures to mitigate the risk of bacterial contamination before they can sell platelets to hospitals. 21 C.F.R. § 606.145. Except as otherwise admitted, the allegations in Paragraph 29 are denied.

IV. FACTUAL ALLEGATIONS

30. Admitted.

31. Admitted.

32. Admitted.

33. The Red Cross admits that Paragraph 33 describes one way that platelets can be collected. Except as otherwise admitted, the allegations in Paragraph 33 are denied.

34. The Red Cross admits that it collects, manufactures and sells doses of platelets to hospitals. The Red Cross further admits that it is considered a “blood establishment” or “blood center” within the meaning of FDA regulations and guidance. Except as otherwise admitted, the allegations in Paragraph 34 are denied.

35. Paragraph 35 purports to state legal conclusions or characterizations of law to which no response is required. To the extent a response is required, the Red Cross denies the allegations in Paragraph 35.

36. The Red Cross is not familiar with the term “plasma platelets” and therefore denies that allegation. The Red Cross admits the remaining allegations in Paragraph 36.

37. The Red Cross admits that platelets donations take longer than whole blood donations. Except as otherwise admitted, the allegations in Paragraph 37 are denied.

38. The Red Cross admits that, from time to time, there have been platelet shortages in the U.S. Except as otherwise admitted, the allegations in Paragraph 38 are denied..

39. The Red Cross admits that it collects, manufactures and sells doses of platelets to hospitals. Except as otherwise admitted, the allegations in Paragraph 39 are denied.

40. The Red Cross lacks knowledge or information sufficient to form a belief as to the truth of the allegation in Paragraph 40 and on that basis denies it.

41. Denied.

42. Denied.

43. The Red Cross admits that Covid-19 contributed to temporary supply shortages of blood products, including platelets. Except as otherwise admitted, the allegations in Paragraph 43 are denied.

44. The Red Cross admits that it declared a “national blood crisis” on January 11, 2022. Except as otherwise admitted, the allegations in Paragraph 42 are denied.

45. Admitted.

46. Admitted.

47. Admitted.

48. The Red Cross lacks knowledge or information sufficient to form a belief as to the truth of the allegation in Paragraph 48 and on that basis denies it.

49. The Red Cross admits that it has used a primary culture to mitigate bacterial risk in platelets. The Red Cross lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 49, and on that basis denies them.

50. The Red Cross lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 50, and on that basis denies them.

51. The Red Cross lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 51, and on that basis denies them..

52. The Red Cross lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 52, and on that basis denies them.

53. The Red Cross admits that in September 2019, the FDA issued guidance to blood centers that stated only three manufacturing methods were acceptable for the purpose of meeting the legal requirements of 21 C.F.R. § 606.145(a): (1) PRT, (2) LVDS and (3) a primary culture by the “blood collection establishment” followed later by a secondary culture or secondary rapid

testing, typically performed by the hospital. Except as otherwise admitted, the Red Cross denies the allegations in Paragraph 53.

54. The Red Cross admits that the FDA's September 2019 guidance was updated in December 2020 and the FDA sought compliance by October 1, 2021. Except as otherwise admitted, the Red Cross denies the allegations in Paragraph 54.

55. The Red Cross admits that, since at least May 2016, federal law has mandated that all blood centers, including the Red Cross, take FDA-approved measures to mitigate the risk of bacterial contamination before they can sell platelets to hospitals. 21 C.F.R. § 606.145. The Red Cross further admits that October 1, 2021 is the deadline the FDA set for blood collection establishments to comply with the FDA's December 2020 guidance. Except as otherwise admitted, the Red Cross denies the allegations in Paragraph 55.

56. The Red Cross admits that federal law requires blood centers to take FDA-approved measures to mitigate the risk of bacterial contamination in platelets. The Red Cross further admits that, to date, the FDA has only approved three manufacturing methods to meet this legal requirement: PRT, LVDS, and a primary culture performed by the blood collection establishment followed by a secondary culture or rapid test typically performed by the hospital. Except as otherwise admitted, the Red Cross denies the allegations in Paragraph 56.

57. Denied.

58. Denied.

59. The Red Cross admits that, to date, the FDA has only approved three manufacturing methods to meet the requirements of federal law: PRT, LVDS, and a primary culture performed by the blood collection establishment followed by a secondary culture or rapid test typically performed by the hospital. The Red Cross denies the other allegations in Paragraph 59.

60. The Red Cross admits that, to date, the FDA has only approved three manufacturing methods to meet the requirements of federal law: PRT, LVDS, and a primary culture performed by the blood collection establishment followed by a secondary culture or rapid test typically performed by the hospital. The Red Cross further admits that these manufacturing methods are not the same and do not offer all the same benefits to hospitals and patients. Except as otherwise admitted, the Red Cross denies the allegations in Paragraph 60.

61. The Red Cross admits that the excerpted language appears in the document referenced and the document otherwise speaks for itself. Except as otherwise admitted, the Red Cross denies the allegations in Paragraph 61.

62. The Red Cross refers to the document referenced for its complete contents and states that the document speaks for itself. Except as otherwise admitted, the Red Cross denies the allegations in Paragraph 62.

63. Admitted.

64. Admitted.

65. Admitted.

66. Denied.

67. Denied.

68. The Red Cross admits that, to date, the FDA has approved platelets manufactured using PRT to be transfused within five days of collection, and the FDA has not yet approved extending PRT platelets to seven days. Except as otherwise admitted, the Red Cross denies the allegations in Paragraph 68.

69. Denied.

70. The Red Cross lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 70, and on that basis denies them.

71. The Red Cross admits that on December 22, 2022, the FDA issued a statement titled “Important Information for Blood Establishments and Transfusion Services Regarding Bacterial Contamination of Platelets for Transfusion.” The statement, which speaks for itself, said: “Since 2018, FDA is aware of a total of 7 septic transfusion reactions These cases occurred in multiple states, and the implicated components were subject to various bacterial risk mitigation strategies including bacterial culture and/or secondary rapid testing prior to release, or processing with an FDA-approved pathogen reduction device prior to transfusion.”¹ Except as otherwise admitted, the Red Cross denies the allegations in Paragraph 71.

72. Admitted.

73. Admitted.

74. The Red Cross lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 74, and on that basis denies them.

75. Admitted.

76. Admitted.

77. The Red Cross admits that LVDS does not degrade platelet quality. Except as otherwise admitted, the Red Cross denies the allegations in Paragraph 77.

78. Admitted.

79. Denied.

80. Denied.

¹ <https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/important-information-blood-establishments-and-transfusion-services-regarding-bacterial-0>.

81. Denied as to the Red Cross. The Red Cross lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 81, and on that basis denies them.

82. Admitted.

83. The Red Cross admits that the FDA's guidance identifies two types of secondary testing, a secondary culture and a rapid test. The Red Cross admits the second and third sentences in Paragraph 83. Except as otherwise admitted, the Red Cross denies the allegations in Paragraph 83.

84. Admitted.

85. Denied.

86. Admitted.

87. The Red Cross admits that PGD*prime* is sold directly to hospitals and that hospital transfusion staff perform the PGD*prime* test at their own time and expense. The Red Cross lacks knowledge or information sufficient to form a belief as to the truth of the other allegations in Paragraph 87, and on that basis denies them.

88. The Red Cross lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 88, and on that basis denies them.

89. Denied.

90. The Red Cross lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 02, and on that basis denies them.

91. Denied.

92. The Red Cross lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 92, and on that basis denies them.

93. The allegations in Paragraph 93 contain undefined terms that are susceptible to different meanings. The Red Cross therefore denies the allegations in Paragraph 93.

94. The allegations in Paragraph 94 contain undefined terms that are susceptible to different meanings. The Red Cross therefore denies the allegations in Paragraph 94.

95. To the extent the allegations in Paragraph 95 refer to the Red Cross, they are denied. To the extent the allegations do not refer to the Red Cross, the Red Cross lacks knowledge or information sufficient to form a belief as to the truth of the allegations, and on that basis denies them.

96. Denied.

97. The Red Cross admits that it announced in July 2020 that it would fully transition to PRT by 2023 and shared a multi-year, phased implementation plan with customers. The Red Cross announced that it would use LVDS-36 as a bridge to facilitate its transition to PRT. Except as otherwise admitted, the Red Cross denies the allegations in Paragraph 97.

98. The Red Cross admits that it announced in July 2020 that it would fully transition to PRT by 2023 and shared a multi-year, phased implementation plan with customers. Except as otherwise admitted, the Red Cross denies the allegations in Paragraph 98.

99. To the extent the allegations in Paragraph 99 refer to the Red Cross, they are denied. To the extent the allegations do not refer to the Red Cross, the Red Cross lacks knowledge or information sufficient to form a belief as to the truth of the allegations, and on that basis denies them.

100. Denied.

101. Denied.

102. Denied.

103. The Red Cross admits that in 2020 it announced a plan to transition to manufacturing all platelets with PRT by 2023. However, the Red Cross continues to sell some LVDS platelets today. Except as otherwise admitted, the Red Cross denies the allegations in Paragraph 103.

104. Denied.

105. Paragraph 105 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 105.

106. Paragraph 106 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 106.

107. Paragraph 107 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 107.

108. Paragraph 108 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 108.

109. Paragraph 109 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 109.

110. Paragraph 110 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 110.

111. Paragraph 111 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 111.

112. Paragraph 112 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 112.

113. Paragraph 113 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 113.

114. Paragraph 114 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 114.

115. Paragraph 115 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 115.

116. Paragraph 116 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 116.

117. Paragraph 117 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 117.

118. Paragraph 118 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 118.

119. Paragraph 119 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 119.

120. Paragraph 120 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies those allegations in Paragraph 120. The Red Cross also denies the remaining allegations in Paragraph 120.

121. Paragraph 121 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies those allegations in Paragraph 121. The Red Cross also denies the remaining allegations in Paragraph 121.

122. The Red Cross admits that in July 2020 it sent its hospital customers a document entitled “The American Red Cross Approach to Platelet Safety, *Implementation Plan for Bacterial Control Strategies*, Frequently Asked Questions,” (“FAQ”) which was updated in September 2020. The document speaks for itself. Except as otherwise admitted, the Red Cross denies the allegations in Paragraph 122.

123. Paragraph 123 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 123. Red Cross denies the remaining allegations in Paragraph 123.

124. The Red Cross admits that its July 2020 FAQ included the text quoted in Paragraph 124, but refers to that full FAQ for its complete contents. Paragraph 124 also contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies those allegations in Paragraph 124. Red Cross denies the remaining allegations in Paragraph 124.

125. The Red Cross admits that its July 2020 FAQ included the text quoted in Paragraph 125, but refers to that full FAQ for its complete contents. Paragraph 125 also contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies those allegations in Paragraph 125. Red Cross denies the remaining allegations in Paragraph 125.

126. The Red Cross admits that its July 2020 FAQ stated: “Red Cross has determined PR platelets are our product of choice to meet the FDA Guidance while also protecting the platelet supply. PR platelets are suspended in PAS and PAS platelets are not licensed for extension to seven days. The net effect is a difference of only ~12 hours in usable shelf-life when comparing PR to LVDS platelets and those additional hours are at the end of platelet life. Platelets have been shown to become senescent and dysfunctional during storage Provision of 7-day platelets would add additional costs and inventory management complexity potentially compromising the platelet supply.” Paragraph 126 also contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies those allegations in Paragraph 126. Red Cross denies the remaining allegations in Paragraph 126.

127. The Red Cross admits that in response to the following question: “What if FDA extends its implementation date for the Bacterial Control Strategies for platelets? Will Red Cross

delay its implementation?” the Red Cross’s July 2020 FAQ stated: “No, the Red Cross is moving forward with its stated approach for platelet safety. To protect the safety and availability of the platelet supply, the Red Cross has begun to execute its transition to a full pathogen reduced supply and will not delay its implementation even if the FDA Guidance is extended.” Paragraph 127 also contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies those allegations in Paragraph 127. Red Cross denies the remaining allegations in Paragraph 127.

128. The Red Cross admits that its July 2020 FAQ included the text quoted in Paragraph 128, but refers to that full FAQ for its complete contents. Paragraph 128 also contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies those allegations in Paragraph 128. Red Cross denies the remaining allegations in Paragraph 128.

129. The Red Cross admits that its July 2020 FAQ included the text quoted in Paragraph 129, but refers to that full FAQ for its complete contents. Paragraph 129 also contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies those allegations in Paragraph 129. Red Cross denies the remaining allegations in Paragraph 129.

130. The Red Cross admits that it published a quarterly newsletter in Winter 2020 that it distributed to customers and published on its website. The Red Cross admits that the newsletter included the text quoted in Paragraph 130 but refers to that full newsletter for its complete contents. Paragraph 130 also contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed

necessary, the Red Cross denies those allegations in Paragraph 130. Red Cross denies the remaining allegations in Paragraph 130.

131. The Red Cross admits that it received a letter from Verax's outside counsel on August 6, 2020 regarding the Red Cross's FAQ. Except as otherwise admitted, the Red Cross denies the allegations in Paragraph 131.

132. The Red Cross admits that it responded to Verax's August 6, 2020 letter and refers to the full content of that response, which includes the following: "We have thoroughly considered your client's concerns and reviewed the document with great care. We believe that the statements you've highlighted are factually correct and not misleading. Nevertheless, as a courtesy to Verax and consistent with our plan to provide hospitals with regular updates, we intend to distribute a new version of the document that should eliminate any issues. The updated version will go out next week, and we will send you a copy at that time. We reserve all rights with regard to allegations in your letter. We are revising the document to accomplish a variety of improvements and our decision to do so is not, and should not be interpreted as, an admission that the original version was misleading in any way." Except as otherwise admitted, the Red Cross denies the allegations in Paragraph 132.

133. Paragraph 133 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies those allegations in Paragraph 133. The Red Cross also denies the remaining allegations in Paragraph 133.

134. Denied.

135. Denied.

136. Denied.

137. Paragraph 137 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies those allegations in Paragraph 137. The Red Cross also denies the remaining allegations in Paragraph 137.

138. Denied.

139. Denied.

140. The Red Cross admits that faculty from the institutions listed in Paragraph 140 signed a letter that was sent to the FDA and refers to the full letter for its complete contents. Paragraph 140 also contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies those allegations in Paragraph 140. The Red Cross also denies the remaining allegations in Paragraph 140.

141. The Red Cross admits that the letter contains the text quoted in paragraph 141 among other text. The letter otherwise speaks for itself. Paragraph 141 also contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies those allegations in Paragraph 141. The Red Cross also denies the remaining allegations in Paragraph 141.

142. The Red Cross refers to the letter itself for its full and accurate content. Paragraph 142 also contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies those allegations in Paragraph 142. The Red Cross also denies the remaining allegations in Paragraph 142.

143. The Red Cross refers to the written statements from AABB itself for their full and accurate content. Paragraph 143 also contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies those allegations in Paragraph 143. The Red Cross also denies the remaining allegations in Paragraph 143.

144. The Red Cross refers to the written statements from AABB itself for their full and accurate content. Paragraph 144 also contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies those allegations in Paragraph 144. The Red Cross also denies the remaining allegations in Paragraph 144.

145. Paragraph 145 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 145.

146. The Red Cross denies that it has any “tying policy.” The Red Cross lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 146 related to members of Congress, and on that basis denies them. The Red Cross denies the remaining allegations in Paragraph 146.

147. Paragraph 147 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 147.

148. Paragraph 148 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 148.

149. Paragraph 149 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 149.

150. Paragraph 150 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 150.

151. Paragraph 151 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 151.

152. Paragraph 152 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 152.

153. Paragraph 153 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 153.

154. Admitted.

155. Paragraph 155 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 155.

156. Paragraph 156 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 156.

157. Denied.

158. The Red Cross refers to the FDA's written statement for the full and accurate contents. The Red Cross denies the remaining allegations in Paragraph 158.

159. The Red Cross refers to the FDA's written statement for the full and accurate contents. The Red Cross denies the remaining allegations in Paragraph 159.

160. The Red Cross lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 160, and on that basis denies them.

161. The Red Cross admits that because the FDA has not approved the Fresenius-Kabi collection kit for seven-day extension for platelets collected in PAS, and because the Red Cross collects all of its platelets in PAS using Fresenius-Kabi's Amicus devices, the FDA does not permit hospitals to extend the shelf-life of Red Cross platelets beyond five days, regardless of the Red Cross's method of mitigating bacterial risk. The Red Cross also admits that, in some circumstances, it is possible for 48-hour LVDS and Secondary Testing to generate 7-day platelets under FDA regulations. The Red Cross denies the remaining allegations in Paragraph 161.

162. Paragraph 162 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 162.

163. The Red Cross lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 163, and on that basis denies them.

164. Paragraph 164 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 164.

165. Paragraph 165 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 165.

166. Paragraph 166 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 166.

167. Paragraph 167 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 167.

168. Paragraph 168 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 168.

169. Paragraph 169 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 169.

170. Paragraph 170 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 170.

171. Paragraph 171 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 171.

172. Paragraph 172 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 172.

173. Paragraph 173 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 173.

174. Paragraph 174 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 174.

175. Paragraph 175 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 175.

176. The Red Cross refers to the written statements from AABB itself for their full and accurate content. Paragraph 176 also contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies those allegations in Paragraph 176.

177. Paragraph 177 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 177.

178. Paragraph 178 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 178.

179. Paragraph 179 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 179.

180. Paragraph 180 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 180.

181. Paragraph 181 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 181.

182. Paragraph 182 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary to those allegations, the Red Cross denies them. The Red Cross lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 182, and on that basis denies them.

183. Paragraph 183 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 183.

184. Paragraph 184 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 184.

185. Paragraph 184 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 184.

V. MARKETS AND MARKET POWER

186. The Red Cross admits that platelets can have different clinical and therapeutic uses than other blood products. Paragraph 186 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the remaining allegations in Paragraph 186.

187. The Red Cross admits that platelets can have different clinical and therapeutic uses than other blood products. Paragraph 187 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the remaining allegations in Paragraph 187.

188. Paragraph 188 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 188.

189. Paragraph 189 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the remaining allegations in Paragraph 189.

190. Paragraph 190 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 190.

191. Paragraph 191 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 191.

192. Paragraph 192 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 192.

193. Paragraph 193 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 193.

194. Paragraph 194 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 194.

195. Paragraph 195 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 195.

196. The Red Cross admits that it is theoretically possible to transfuse platelets without mitigating bacterial risk at all; however, under federal law today, the Red Cross cannot provide platelets to hospitals until after it has performed one of the three FDA-approved steps for bacterial mitigation. Paragraph 196 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the remaining allegations in Paragraph 196.

197. Paragraph 197 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 197.

198. Paragraph 198 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 198.

199. Paragraph 199 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 199.

200. Paragraph 200 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 200.

201. Paragraph 201 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 201.

202. Paragraph 202 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 202.

203. Paragraph 203 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 203.

204. Paragraph 204 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 204.

205. Paragraph 205 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 205.

206. Paragraph 206 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 206.

207. Paragraph 207 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 207.

208. Paragraph 208 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 208.

209. Paragraph 209 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 209.

210. Paragraph 210 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 210.

211. Paragraph 211 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 211.

212. Paragraph 212 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 212.

213. Paragraph 213 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 213.

214. The Red Cross lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 214, and on that basis denies them.

215. Paragraph 215 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 215.

216. The Red Cross admits that some hospitals choose to purchase all of their platelets from the Red Cross. Paragraph 216 also contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the remaining allegations in Paragraph 216.

217. Paragraph 217 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 217.

218. Paragraph 218 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 218.

219. Paragraph 219 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 219.

220. Paragraph 220 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 220.

221. Paragraph 221 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 221.

222. Paragraph 222 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 222.

223. Paragraph 223 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 223.

224. Paragraph 224 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 224.

225. Paragraph 225 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 225.

226. The Red Cross admits that platelets are regulated by the FDA. The Red Cross further admits that blood centers have to comply with registration requirements, clinical standards, reporting requirements, and monitoring and inspection protocols. Paragraph 226 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order,

and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 226.

227. Paragraph 227 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 227.

228. Paragraph 228 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 228.

229. Paragraph 229 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 229.

VI. ANTICOMPETITIVE EFFECTS AND ANTITRUST INJURY

230. Paragraph 230 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 230.

231. Paragraph 231 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 231.

232. Paragraph 232 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 232.

233. Paragraph 233 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 233.

234. Paragraph 234 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 234.

235. Paragraph 235 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 235.

236. Paragraph 236 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 236.

237. Paragraph 237 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 237.

238. Paragraph 238 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 238.

239. Paragraph 239 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 239.

240. Paragraph 240 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 240.

241. Paragraph 241 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 241.

242. Paragraph 242 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 242.

243. Paragraph 243 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 243.

244. Paragraph 244 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 244.

245. Paragraph 245 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 245.

246. Paragraph 246 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 246.

247. Paragraph 247 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 247.

248. Paragraph 248 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 248.

249. Paragraph 249 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 249.

250. Paragraph 250 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 250.

251. Paragraph 251 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 251.

252. Paragraph 252 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 252.

253. Paragraph 253 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 253.

254. Paragraph 254 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 254.

255. Paragraph 255 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 255.

256. Paragraph 256 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 256.

VII. CAUSES OF ACTION

COUNT ONE **(Tying)**

257. Paragraph 257 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 257.

258. Paragraph 258 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 258.

259. Paragraph 259 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 259.

260. Paragraph 260 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 260.

261. Paragraph 261 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 261.

262. Paragraph 262 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 262.

263. Paragraph 263 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 263.

264. Paragraph 264 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 264.

265. Paragraph 265 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 265.

266. Paragraph 266 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 266.

267. Paragraph 267 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 267.

268. Paragraph 268 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 268.

269. Paragraph 269 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 269.

270. Paragraph 270 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 270.

271. Paragraph 271 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 271.

272. Paragraph 272 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 272.

273. Paragraph 273 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 273.

274. Paragraph 274 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 274.

275. Paragraph 275 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 275.

COUNT TWO
(Exclusive Dealing)

276. Paragraph 276 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 276.

277. Paragraph 277 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 277.

278. Paragraph 278 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 278.

279. Paragraph 279 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 279.

280. Paragraph 280 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 280.

281. Paragraph 281 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 281.

282. Paragraph 282 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 282.

283. Paragraph 283 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 283.

284. Paragraph 284 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 284.

285. Paragraph 285 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 285.

COUNT THREE

(Attempted Monopolization of U.S. Market for Platelet Bacteria Mitigation Services)

286. Paragraph 286 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 286.

287. Paragraph 287 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 287.

288. Paragraph 288 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 288.

289. Paragraph 289 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 289.

290. Paragraph 290 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 290.

291. Paragraph 291 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 291.

292. Paragraph 292 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 292.

293. Paragraph 293 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 293.

294. Paragraph 294 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 294.

295. Paragraph 295 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 295.

296. Paragraph 296 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 296.

297. Paragraph 297 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 297.

298. Paragraph 298 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 298.

299. Paragraph 299 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 299.

300. Paragraph 300 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 300.

301. Paragraph 301 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 301.

302. Paragraph 302 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 302.

303. Paragraph 303 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 303.

304. Paragraph 304 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 304.

305. Paragraph 305 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 305.

COUNT FOUR
(Unfair Methods of Competition and Unfair and Deceptive Practices)

306. The Red Cross incorporates and re-asserts each response to each allegation above as if fully set forth herein.

307. The Red Cross admits that Verax sells its PGD*prime* test in the United States. The Red Cross lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 307, and on that basis denies them.

308. The Red Cross admits that it sells platelets in the United States, including in Massachusetts. The Red Cross denies the remaining allegations in Paragraph 308.

309. Paragraph 309 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies those allegations in Paragraph 309. The Red Cross also denies the remaining allegations in Paragraph 309.

310. Denied.

311. Denied.

312. Denied.

313. The Red Cross admits that it received a letter from Verax before Verax filed its Complaint, but the Red Cross denies that it has engaged in any unfair methods of competition. The Red Cross denies the remaining allegations in Paragraph 313.

314. The Red Cross denies that it has engaged in any unfair methods of competition, and denies the allegations in Paragraph 314.

315. The Red Cross denies that it has engaged in any unfair methods of competition, and denies the allegations in Paragraph 315.

316. The Red Cross admits that Verax contends its principal place of business is within Massachusetts and that Verax sells its *PGDprime* test from Massachusetts to customers in Massachusetts. However, the Red Cross lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 316, and on that basis denies them.

317. The Red Cross admits that it sells platelets in Massachusetts. The Red Cross denies the remaining allegations in Paragraph 317.

318. Denied.

319. Denied.

320. Denied.

COUNT FIVE
(Defamation)

321. Paragraph 321 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 321.

322. Paragraph 322 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 322.

323. Paragraph 323 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 323.

324. Paragraph 324 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 324.

325. Paragraph 325 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 325.

326. Paragraph 326 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 326.

327. Paragraph 327 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 327.

328. Paragraph 328 contains allegations and legal argument that relate to claims the Court dismissed in its January 19 Order, and thus no response is required. If a response is deemed necessary, the Red Cross denies the allegations in Paragraph 328.

COUNT SIX
(Tortious Interference with Contractual Relations)

329. The Red Cross incorporates and re-asserts each response to each allegation above as if fully set forth herein.

330. The Red Cross lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 330, and on that basis denies them.

331. Denied.

332. Denied.

333. Denied.

334. Denied.

RESPONSE TO PRAYER FOR RELIEF

Verax's Prayer for Relief does not contain any factual assertions to which a response is required. To the extent a response is required, the Red Cross denies that Verax is entitled to any of the relief it requested, including injunctive relief, damages, pre- and post-judgment interest, costs, expenses, reasonable attorneys' fees, or any other kind of relief. All allegations of the Complaint not previously admitted or denied are here and now denied as though specifically denied herein.

RESPONSE TO DEMAND FOR JURY TRIAL

The Red Cross admits that Verax demands a jury trial on all issues so triable, but does not concede Verax is entitled to a jury trial.

AFFIRMATIVE DEFENSES

Without assuming any burden that it would not otherwise bear, the Red Cross asserts the following defenses to Verax's two claims that survived the Red Cross's motion to dismiss (Counts Four and Six). The Red Cross reserves all affirmative defenses under Rule 8(c) of the Federal Rules of Civil Procedure and Massachusetts General Laws Chapter 93A and any other defenses at law or in equity that may exist now or that may be available in the future based on discovery and further factual investigation in this action.

FIRST DEFENSE
(Justified Conduct/Government Action)

Verax's claims are barred, in whole or in part, because all of the Red Cross's challenged conduct was lawful, fair, not deceptive, expressly authorized by law, and justified. The challenged conduct constituted a legitimate business practice consistent with industry norms and was carried out by a federal instrumentality in furtherance of federal law and the Red Cross's statutorily mandated obligations.

SECOND DEFENSE
(Failure To Mitigate)

Verax's claims are barred, in whole or in part, because it failed to exercise reasonable care to mitigate any damages it may have suffered.

THIRD DEFENSE
(Lack of Proximate Cause and Intervening/Superseding Conduct)

Verax's claims are barred, in whole or in part, because any alleged injuries and damages either were not legally or proximately caused by any acts or omissions of the Red Cross or were caused, if at all, solely and proximately by Verax's conduct or by the conduct of third parties.

FOURTH DEFENSE
(Federal Instrumentalities Are Not Subject to Massachusetts General Laws Chapter 93A)

Count IV (Unfair Methods of Competition and Unfair and Deceptive Practices) is barred because the Red Cross is a federal instrumentality and federal instrumentalities are not subject to liability under Mass. Chap. 93A.

FIFTH DEFENSE
(Alleged Misconduct Not Primarily & Substantially in Massachusetts)

Count IV (Unfair Methods of Competition and Unfair and Deceptive Practices) is barred because the alleged actionable conduct did not occur primarily and substantially within Massachusetts.

SIXTH DEFENSE
(Non-Profit Not Engaged in “Trade or Commerce”)

Count IV (Unfair Methods of Competition and Unfair and Deceptive Practices) is barred because the Red Cross is not a “person” engaged in “trade or commerce.”

PRAYER FOR RELIEF

WHEREFORE, Defendant, Red Cross, respectfully requests that this Court enter a judgment in its favor and against Plaintiff, Verax, by granting the following relief:

- A. Entering judgment in the Red Cross’s favor on all the remaining claims set forth in Verax’s Complaint and dismissing each claim with prejudice;
- B. Granting the Red Cross such other and further relief, in law or equity, as the Court deems just and proper, including any entitlement to costs or attorneys’ fees.

Dated: February 23, 2024

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that the foregoing document, which was filed with the Court through the CM/ECF system, will be sent electronically to all registered participants as identified on the Notice of Electronic Filing (“NEF”) and paper copies will be sent on February 23, 2024 to those identified as nonregistered participants.

/s/ William J. Trach
William J. Trach